MAY 2 8 2004

Pg 1 of 2 K041117

510(k) Summary – Panalok RC QuickAnchor Plus and Dual Suture Panalok RC QuickAnchor Plus

Submitter's Name and Address:

DePuy Mitek
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, MA 02062

Contact Person

Allyson Barford
Regulatory Affairs Associate
DePuy Mitek
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, MA 02062
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Name of Medical Device

Classification Name: Screw, Fixation, Bone Staple

Common/Usual Name: Appliance for reconstruction of bone to soft tissue

Proprietary Name: Panalok RC QuickAnchor Plus
Dual Suture Panalok RC QuickAnchor Plus

Device Classification

Screw, Fixation, Bone Staple devices have been classified as Class II, GAM and MAI according to 21 CFR 888.3030. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Screw, Fixation, Bone Staple devices.

Indications for Use

The Mitek Panalok RC QuickAnchor Plus and Dual Suture Panalok RC QuickAnchor Plus Anchors are intended for fixation of USP size #2 suture to bone for the indication listed below.
Shoulder: Rotator cuff repair.

Device Description

The PANALOK RC QuickAnchor Plus is a preloaded disposable anchor/inserter assembly system designed to facilitate the fixation of USP size #2 suture to bone. The absorbable polylactic acid (PLA) anchor is the identical anchor as that of the Mitek Toggle Anchor, and the sutures are similar to those used in the Mitek Toggle Anchor

System and other Mitek Anchor systems. The Panacryl and Ethibond sutures are manufactured by Ethicon, Inc. The absorbable anchor is a one-piece suture anchor constructed of molded Poly(L-lactide) polymer.

The Dual Suture PANALOK RC QuickAnchor Plus is preloaded disposable anchor/inserter assembly system designed to facilitate the fixation of USP size #2 suture to bone. The absorbable polylactic acid (PLA) anchor is similar to the Mitek Toggle Anchor; the only change is a dimensional change to accommodate two strands of suture instead of one. The sutures are similar to those used in the Mitek Toggle Anchor System and other Mitek Anchor systems. The Panacryl and Ethibond sutures are manufactured by Ethicon, Inc. The absorbable anchor is a one-piece suture anchor constructed of molded Poly(L-lactide) polymer.

Substantial Equivalence

Based on the degree of changes being made to the original Mitek Absorbable Toggle Anchor (K964013) and the fact that the Panalok RC QuickAnchor Plus and Dual Suture Panalok RC QuickAnchor Plus represent the same fundamental scientific technology as the original Mitek Absorbable Toggle Anchor; Mitek believes that the Panalok RC QuickAnchor Plus and Dual Suture Panalok RC QuickAnchor Plus are substantially equivalent to the Mitek Absorbable Toggle Anchor manufactured by DePuy Mitek.

Safety

Biocompatibility studies have demonstrated the Panalok RC QuickAnchor Plus and Dual Suture Panalok RC QuickAnchor Plus Anchors to be non-toxic, non-irritating, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2004

Allyson Barford
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Norwood, Massachusetts 02062

Re: K041117
Trade/Device Name: Panalok RC QuickAnchor Plus
Dual Suture Panalok RC QuickAnchor Plus
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: April 5, 2004
Received: April 29, 2004

Dear Ms. Barford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K041117

Device Names:

Panalok RC QuickAnchor Plus
Dual Suture Panalok RC QuickAnchor Plus

Indications for Use:

The Panalok RC QuickAnchor Plus and Dual Suture Panalok RC QuickAnchor Plus are intended for fixation of USP size #2 suture to bone for the indication listed below.
Shoulder: Rotator cuff repair.

Mark N Milham

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041117

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____